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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/506,454 | 08/04/2005 | Alexei Slesarev | FID001 US | 8305 |
| 25235 7590 01/11/2007 HOGAN & HARTSON LLP ONE TABOR CENTER, SUITE 1500 1200 SEVENTEENTH ST DENVER, CO 80202 | | | EXAMINER KELLY, ROBERT M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |

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| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
| 31 DAYS | 01/11/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/506,454

Applicant(s)

SLESAREV ET AL.

Examiner

Robert M. Kelly

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-31 are presently pending and subject to the following restriction and election requirements.

Notes to Applicant

It is noted that Applicant's claims use terminology that is not allowed in US practice, e.g., "Use" terminology, and further claims references to sequences by an attachment listing. The Examiner cannot search the sequences, without specific listing of SEQ ID NO. and further, such necessarily frustrates the ability of the Examiner to provide a comprehensive action, and it is advised that the terminology be fixed prior to the first examination on the merits. Further, with regard to use claims, such have been interpreted as method claims and grouped according to the description given in the specification, as such appears to be the most reasonable interpretation, however, amending the claims to reflect the use, or simplify them to contain only a composition, is recommended to avoid non-statutory claim terminology and obtain a comprehensive prosecution.

Second, it is noted that page 11 of the specification leads to a lack of clarity as what each SEQ ID NO is, i.e., the statement "The genes predicted with these methods in the regions between evolutionarily conserved genes were added to produce the final protein set. (See Attachment B SEQ ID Nos.; 1-1691) 1-1688 and 1690-1692." Lacks clarity such the Examiner determine what is protein and/or nucleic acid sequence, and what sequence(s) are the whole genome of *M. kandleri*. Applicant is requested to clear up these issues so that a comprehensive and compact prosecution can be returned to Applicant upon response to this requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 8-11, 19, 21, 32, drawn to a nucleic acid encoding a protein of *M. kandleri*, host cells which can express the protein encoded, and methods of expressing a the protein encoded.

Group II, claim(s) 4-6 and 22-23, drawn to polypeptides encoded by *M. kandleri*.

Group III, claim(s) 7, 23, drawn to antibody compositions, which bind to a protein encoded by *M. kandleri*.

Group IV, claim(s) 12-15, drawn to computer readable media which comprises a sequence with at least 70% identity to SEQ ID NO: 1692.

Group V, claim(s) 17-18, drawn to a method to identify an amino acid sequence from SEQ ID NO: 1693.

Group VI, claim(s) 20, drawn to a method to identify a protein with an antibody to an *M. kandleri* protein.

Group VII, claim(s) 24 and 26, drawn to a method of treatment, comprising administration of a nucleic acid encoding a protein of *M. kandleri*.

Group VIII, claim(s) 24 and 26, drawn to a method of treatment comprising administration of a protein encoded by the genome of *M. kandleri*.

Group IX, claim(s) 24 and 26, drawn to a method of treatment comprising administration of an antibody to a protein encoded by *M. kandleri*.

Group X, claim(s) 25, drawn to a method to stabilize a protein comprising exposure to nucleic acid encoding a protein from the genome of *M. kandleri*.

Group XI, claim(s) 25 and 28-30, drawn to a method to stabilize a protein comprising exposure to a protein encoded by *M. kandleri*.

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Group XII, claim(s) 25, drawn to a method to stabilize a protein comprising exposure to an antibody which recognizes a protein encoded by *M. kandleri*.

Group XIII, claim(s) 27, drawn to a protein stabilizable by the presence of a protein encoded by *M. kandleri*.

Group XIV, claim(s) 31, drawn to a composition comprising a protein encoded by *M. kandleri* and a second protein not encoded by *M. kandleri*.

The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature shared by any two groups is the protein or nucleic acid encoding such, from *M. kandleri*. Pavlov, et al. (February 2002) Nucl. Acids Res., 30(3): 685-94 discloses three novel DNA binding proteins from such organism (e.g., ABSTRACT), and hence, the specific technical feature, the protein, and from the protein, the inventive step to get to the nucleic acid is obvious, as cloning techniques are well known in the Art, the practitioner would do it in order obtain the nucleic acid sequence proteins, and would do so in order to perform the experiments of Pavlov, and would expect it to be successful, as the methods are well within the skill of those in the art. Further, the individual inventions require separate considerations, as they have distinct structural and functional characteristics, as follows: Group I requires a consideration of the nucleic acid structure which can be used in any particular assay, such as hybridization, Group II requires a consideration of the structure which can be used in any particular protein assay, such as hybridization assays, Group III requires a consideration of the structure required to bind the protein and how it may be used in any particular assay such as immunoblots or therapy, Group IV requires a consideration of computer media and how to use it, Group V requires a consideration of the methods of identifying the genes, Group VI requires a consideration of how to apply an antibody to identify a protein, Groups VII-IX require a consideration of the structure of the nucleic acid, protein, or antibody used in treatment and how to apply which are distinct because of their structures being distinct, Groups X-XII require a consideration of the structure of any particular protein, nucleic acid or antibody and how it will stabilize any particular protein, Group XIII requires a consideration of the proteins which may be stabilized by any particular protein, and Group XIV requires a consideration of the interaction of the proteins of the composition and to what use this interaction is provided. Hence, due to the distinct structural considerations, leading to distinct functional considerations of each invention, it is clear that the search and examination of any particular invention would not necessarily yield the art to search and examine any other invention. Hence, it would pose a serious burden on the Examiner to search and examine more than one invention, and therefore, there exists no general inventive concept.

Further Restriction Requirement:

The following restriction requirement, although written as a species election, is a further restriction of the inventions, and not simply a species requirement.

The following restriction is required for Inventions I-III and VI-XIV (I.e., if Applicant Elects any of inventions I-III or VII-XIV, Applicant must further elect a single species as below, to which the invention will be restricted.)

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to choose a **single** SEQ ID NO of SEQ ID NOs: 1-1688 or 1690-1692 (or such other single sequence reflecting a single protein or encoded protein, as supported by the specification and/or claims).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As shown above, Pavlov identified proteins and the Artisan would further find the nucleic acids to lack an inventive step. Further, each nucleic acid and protein is distinct in structure, and therefore has distinct functions, providing distinct effects and it would pose a serious burden on the examiner to search and examine more than one invention, because the Art would not necessarily be yielded to search and examine any other invention, due to the structural and functional differences. Hence, there exists no general inventive concept.

The following species requirements are further required if Applicant elects an invention chosen from the group consisting of XIII and XIV

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to choose a single second protein, not of the SEQ ID NOs provided, which is supported by the specification.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 27 and 31.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the claims encompass an essentially limitless number of known and unknown proteins, each having distinct structure, and therefore, the manner and mechanisms which such compositions may stabilize or be put to other benefit requires distinct considerations such that it would pose a serious burden on the Examiner to search and examine any two proteins together. Hence, the species share no single general inventive concept.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

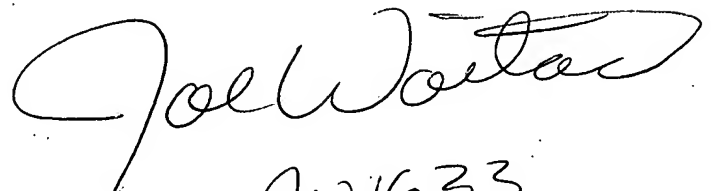
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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